

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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AT 8:30
WILLIAM T. WALSH
CLERK

SANOFI-AVENTIS,)	
SANOFI-AVENTIS U.S. LLC, AND)	
DEBIOPHARM S.A.,)	
)	
Plaintiffs,)	Civil Action No. 3:07-cv-02762-JAP-DEA
)	Civil Action No. 3:08-cv-02693-JAP-JJH
v.)	Civil Action No. 3:07-cv-03164-JAP-JJH
)	Civil Action No. 3:08-cv-06243-JAP-JJH
)	Civil Action No. 3:07-cv-01116-JAP-DEA
SANDOZ INC.,)	(No. 3:07-cv-02762 - consolidated)
)	
Defendant.)	
)	

FINDINGS OF FACT AND CONSENT JUDGMENT AND ORDER

The Court, upon the consent and request of Plaintiffs Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Debiopharm S.A. (collectively, "Sanofi-Aventis," "Debiopharm," or "Plaintiffs") and Defendants Sandoz Inc. and Ebewe Pharma Ges.m.b.H. Nfg.KG (hereinafter, "Sandoz", "Ebewe" or collectively "Defendants"), and in furtherance of the Settlement Agreement (the "Settlement Agreement") and the License Agreement attached thereto (the "License Agreement") entered into by and among Plaintiffs and Defendants, hereby makes the following Findings of Fact and issues the following Consent Judgment and Order, which supersedes the Ebewe Consent Judgment and Order dated July 9, 2009:

FINDINGS OF FACT

1. This Court has subject matter jurisdiction over the above captioned patent infringement action (the "Action") and personal jurisdiction over Sanofi-Aventis, Debiopharm, Sandoz and Ebewe. Venue is proper in this Court as to Sanofi-Aventis, Debiopharm, Sandoz and Ebewe.
2. In this Action, Sanofi-Aventis and Debiopharm have charged Sandoz with infringement of United States Patent No. 5,338,874 ("the '874 Patent") and United States Patent

No. 5,716,988 ("the '988 Patent") (collectively, the "patents in suit") in connection with Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 78-817 directed to a generic oxaliplatin injection (5 mg/mL, 10 mL, 20 mL, and 40mL vials) to the U.S. Food and Drug Administration ("FDA"). Plaintiffs have additionally charged Ebewe with infringement of the '874 patent and '988 patent in connection with Ebewe's submissions of ANDA Nos. 78-812 and 90-849 to the FDA. ANDA No. 78-812 is directed to generic oxaliplatin injection (5 mg/ml in 10 mL and 20 mL vials) and ANDA No. 90-849 is directed to generic oxaliplatin for injection (50 mg/vial, 100 mg/vial and 200 mg/vial).

3. In response to the charges by Sanofi-Aventis and Debiopharm of patent infringement, Defendants have alleged certain defenses and counterclaims, including that the '874 and '988 Patents are invalid, unenforceable, and not infringed by Defendants' generic oxaliplatin products defined by ANDA Nos. 78-812, 78-817 and 90-849 ("Defendants' Product") and that various aspects of Plaintiffs' conduct concerning the Patents and the oxaliplatin products developed therefrom violates the antitrust laws of the United States.

4. Sanofi-Aventis and Debiopharm have agreed that each of the claims set forth in its Complaints against Defendants (including amendments) in each of the above-captioned matters, including the allegations and averments contained therein, should be dismissed, with prejudice in accordance with the terms of the following Consent Judgment and Order.

5. Ebewe and Sandoz have agreed that each of the defenses and counterclaims set forth in its Answers and Counterclaims in each of the above-captioned matters, including the allegations and averments contained therein, should be dismissed, with prejudice in accordance with the terms of the following Consent Judgment and Order.

6. Plaintiffs acknowledge that Sandoz and Ebewe (now a Sandoz affiliate) maintain their Paragraph IV certifications to the '874 and '988 patents pursuant to 21 C.F.R. § 314.94(a)(12)(v).

CONSENT JUDGMENT AND ORDER

Accordingly, pursuant to the above Findings of Fact, and upon the consent and request of Sanofi-Aventis, Debiopharm, Sandoz and Ebewe, **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:**

1. This Consent Judgment and Order is effective as of the effective date of the Settlement Agreement.
2. This Action is hereby stayed (the "Stay") as of the effective date of this Consent Judgment and Order, subject to the terms and conditions below.
3. If, as of June 30, 2010, (i) neither Sun Pharmaceutical Industries Ltd. ("Sun") nor its Affiliates is prohibited from marketing Generic Equivalent (as defined in the Settlement Agreement), and (ii) the Injunction Date (as defined in the Settlement Agreement) would have occurred on June 30, 2010 if Sun or its Affiliates were prohibited from marketing Generic Equivalent on that date, then, effective as of July 1, 2010 (a) the Stay is hereby temporarily lifted for the period commencing on July 1, 2010 and ending on July 12, 2010 (the "Interim Period"), and (b) Defendants and its Affiliates are hereby enjoined from manufacturing, using, or selling within the United States, or importing into the United States, Defendants' Product during the Interim Period.
4. If at the end of the Interim Period, Sun and its Affiliates are enjoined from Selling Generic Equivalent, and only if all other conditions for the occurrence of an Injunction Date under the Settlement Agreement have been satisfied, then, effective on the first day following the Interim Period, (i) each of the following claims, defenses and counterclaims is hereby dismissed with prejudice (a) each of Sanofi-Aventis' and Debiopharm's claims with respect to Defendants' ANDA Nos. 78-812, 78-817 and 90-849 and (b) each of Defendants' defenses and counterclaims with respect to the '874 Patent and '988 Patent (ii) Defendants and its Affiliates are hereby enjoined from manufacturing, using, or selling within the United States,

or importing into the United States Defendants' Product during the life of the '874 Patent and '988 Patent, including any extensions and pediatric exclusivity, until the occurrence of a Launch Date under the License Agreement, or as otherwise permitted under 35 U.S.C. § 271(e)(1), unless all of the asserted and adjudicated claims of the '874 Patent and '988 Patent are found invalid or unenforceable by a decision of a United States court from which no appeal has been or can be taken, other than pursuant to an en banc review at the Court of Appeals for the Federal Circuit or a writ of certiorari or other proceedings before the U.S. Supreme Court; and (iii) with applicability in the United States only and exclusive to the Defendants' Products, Defendants admit that the '874 Patent and '988 Patent are valid and enforceable, and that absent a license from Plaintiffs, the manufacture, use or sale of the Defendants' Products have infringed and would infringe the '874 Patent and '988 Patent.

5. If at the end of the Interim Period, Sun and its Affiliates are not enjoined from Selling Generic Equivalent, then (a) the Stay is hereby reinstated effective on the first day following the Interim Period and (b) the injunction under Section 3(b) above shall be of no force or effect thereafter.

6. If, between the first day following the Interim Period and March 31, 2011, Sun and its Affiliates are enjoined from Selling Generic Equivalent and the Injunction Date has occurred, then effective on the Injunction Date (as determined under the Settlement Agreement), (i) each of the following claims, defenses and counterclaims is hereby dismissed with prejudice (a) each of Sanofi-Aventis' and Debiopharm's claims with respect to Defendants' ANDA Nos. 78-812, 78-817 and 90-849; (b) each of Defendants' defenses and counterclaims with respect to the '874 Patent and '988 Patent and (ii) Defendants and its Affiliates are hereby enjoined from manufacturing, using, or selling within the United States, or importing into the United States Defendants' Product during the life of the '874 Patent or '988 Patent, including any extensions and pediatric exclusivity, until the occurrence of a Launch Date under the License Agreement, or

as otherwise permitted under 35 U.S.C. § 271(e)(1), unless all of the asserted and adjudicated claims of the '874 Patent or '988 Patent are found invalid or unenforceable by a decision of a United States court from which no appeal has been or can be taken, other than pursuant to an en banc review at the Court of Appeals for the Federal Circuit or a writ of certiorari or other proceedings before the U.S. Supreme Court; and (iii) with applicability in the United States only and exclusive to the Defendants' Products, Defendants admit that the '874 Patent and '988 Patent are valid and enforceable, and that absent a license from Plaintiffs, the manufacture, use or sale of the Defendants' Products have infringed and would infringe the '874 Patent and '988 Patent.

7. If a Launch Date occurs prior to either or both of the Injunction Date and March 31, 2011, then, effective on such Launch Date, each of the following claims, defenses and counterclaims is hereby dismissed with prejudice (a) each of Sanofi-Aventis' and Debiopharm's claims with respect to Defendants' ANDA Nos. 78-812, 78-817 and 90-849 and (b) each of Defendants' defenses and counterclaims with respect to the '874 Patent and '988 Patent; and (ii) with applicability in the United States only and exclusive to the Defendants' Products, Defendants admit that the '874 Patent and '988 Patent are valid and enforceable, and that absent a license from Plaintiffs, the manufacture, use or sale of the Defendants' Products have infringed and would infringe the '874 Patent and '988 Patent.

8. On March 31, 2011, if the Injunction Date has not occurred, then the Settlement Agreement will terminate in accordance with Section 9(b) thereof and these Findings of Fact and Consent Judgment and Order shall be null and void.

9. If the Settlement Agreement and License Agreement between Defendants and Plaintiffs are terminated by any party under Section 2.6 of the Settlement Agreement, then these Findings of Fact and Consent Judgment and Order shall be null and void, and the Ebewe Consent Judgment and Order dated July 9, 2009 shall be null and void.

10. Except with respect to monetary damages for at-risk sales occurring after February 1, 2010 until the earlier of the Injunction Date or the Launch Date in excess of the Sandoz Milligram Amount as provided in Section 5 of the Settlement Agreement, each of Sanofi-Aventis and Debiopharm, on behalf of itself and its Affiliates, expressly waives any right or interest in or to any monetary damages, liabilities or remedies, of any kind, based on Defendants' unlicensed and infringing sales, prior to the earlier of the Injunction Date or the Launch Date, of Defendants' Products.

11. Sanofi-Aventis, Debiopharm, Sandoz and Ebewe each expressly waives any right to appeal or otherwise move for relief from these Findings of Fact and Consent Judgment and Order.

12. This Court retains continuing jurisdiction to adjudicate any disputes arising out of the Settlement Agreement and the License Agreement and to enforce these Findings of Fact and Consent Judgment and Order.

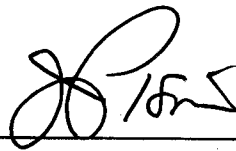
13. Unless this Consent Order and Judgment terminates pursuant to Sections 8 or 9 above, these Findings of Fact and Consent Judgment and Order shall finally resolve this Action between Sanofi-Aventis, Debiopharm, Sandoz and Ebewe. Each party shall bear its own costs and fees, including attorney fees.

14. The Clerk of the Court is directed to enter this Consent Judgment and Order forthwith.

SO ORDERED:

This 14th day of April, 2010

HONORABLE JOEL A. PISANO
UNITED STATES DISTRICT JUDGE



A handwritten signature in black ink, appearing to read 'JP/10/10', is written over a horizontal line.